

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1646 RECEIVED

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In Re the Application of: OLWIN et al.

Serial No.: 09/377,675

Filed: August 19, 1999

Atty. File No.: 2848-32

For: "CHIMERIC FIBROBLAST GROWTH

> FACTOR PROTEINS, NUCLEIC ACID MOLECULES, AND USES THEREOF" )

**Assistant Commissioner For Patents** Washington, D.C. 20231

CERTIFICATE OF MAILING

**RESPONSE TO COMMUNICATION** FROM EXAMINER

Group Art Unit: 1646

Examiner: Chernyshev, O.

HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO THE ASSISTANT COMMISSI PATENTS, WASHINGTON, DC 20231 QN

Dear Sir:

This response is filed in response to a Communication from the Examiner mailed September 20, 2002. This response is believed to be timely and therefore, no fees are enclosed. In the event that fees are due in connection with this response, please debit Deposit Account No. 19-1970.

## **REMARKS**

The Examiner contends that the above-identified application fails to comply with the requirements of 37 CFR § 1.821-1.825. Provision of a substitute computer readable form and paper copy of the Sequence Listing has been required. Specifically, the Examiner asserts that "no sequence listing has been provided that includes the amino acid sequence presented in claim 9 and on page 5 of the instant specification." The Examiner has also required that the specification be amended to recited the new sequence identifier wherever the reference is made to that sequence.

Applicants respectfully respond that 37 CFR § 1.821-1.825 does not require that a sequence identifier be provided for the type of amino acid sequence set forth in claim 9 and on page 5 of the specification. Claim 9 reads as follows:

- 9. The chimeric fibroblast growth factor (FGF) of Claim 1, wherein said penetratin peptide is selected from the group consisting of:
  - a. a first peptide having an amino acid sequence selected from the group consisting of:
    - i.  $X_1 X_2 X_3 X_4 X_5 X_6 X_7 X_8 X_9 X_{10} X_{11} X_{12} X_{13} X_{14} X_{15} X_{16}$ ; and,
    - ii.  $X_{16}-X_{15}-X_{14}-X_{13}-X_{12}-X_{11}-X_{10}-X_9-X_8-X_7-X_6-X_5-X_4-X_3-X_2-X_1;$  wherein  $X_1, X_2, X_3, X_4, X_5, X_7, X_8, X_9, X_{10}, X_{11}, X_{12}, X_{13}, X_{14},$   $X_{15}$ , and  $X_{16}$  each represent an  $\alpha$ -amino acid, between 6 and 10 of which are hydrophobic amino acids; and wherein  $X_6$  represents Trp; and,
  - b. a second peptide comprising amino acid residues 49-57 of HIV Tat protein (SEQ ID NO:17).

The Examiner contends that the sequences in Claim 9(a)(i) & (ii) should be represented by sequence identifiers. The rules governing whether or not a given amino acid sequence must be represented by a sequence identifier read as follows (37 CFR § 1.821(a)):

Nucleotide and/or amino acid sequences as used in §§ 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids....Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. 'Specifically defined' means those amino acids other than 'Xaa'...

The two amino acid sequences recited in Claim 9 each have 16 amino acid residues defined by "X," wherein 15 out of the 16 amino acids represent any  $\alpha$ -amino acid, between 6 and 10 of which are hydrophobic amino acids, and wherein only <u>one</u> of the 16 amino acids is <u>specifically defined</u> (i.e., position  $X_6$  is Trp). Therefore, the sequences in Claim 9 and on page 5 of the specification contain less than 4 specifically defined amino acid residues and are thus exempt from the requirement for a sequence identifier.

Applicants agent also contacted Robert Wax of the U.S. Patent Office to confirm that the requirements of 37 CFR § 1.821-1.825 were being correctly interpreted with regard to the sequences in Claim 9. Applicants agent recited the limitations of the sequences in Claim 9 and Dr. Wax responded by a voice mail confirming that no sequence identifier is required by 37 CFR § 1.821-1.825 for these sequences.

In view of the foregoing remarks, Applicants respectfully request that the Examiner withdraw the requirement for a substitute Sequence Listing and amendments to the specification. In the event that the Examiner has any questions regarding Applicants' position, please contact the below-named agent.

Respectfully submitted,

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Date: October 9, 2002